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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/893,759	07/11/97	SAITOH	K 1587-0024-0
			EXAMINER

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18N2/0204

SP-1000	PAPER NUMBER
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1817

DATE MAILED: 02/04/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-6 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-6 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☒ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

(see paper no. 3  
Submitted 7/11/97)

\*Certified copies not received: \_\_\_\_\_

- ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2 (Submitted 11/17/97).
- ☒ Interview Summary, PTO-413 (encl)
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1817

***PRIORITY DOCUMENT RECEIVED***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***DRAWINGS***

The drawings filed July 11, 1997 are not objected to by the Draftsperson under 37 CFR 1.84 or 1.152.

***ABSTRACT***

The abstract of the disclosure is objected to because it should be a single paragraph; and, it should not refer to purported merits or speculative applications of the invention. Correction is required. See MPEP § 608.01(b).

***TITLE***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

***INFORMALITIES***

The disclosure is objected to because of the following informalities: abbreviations should be fully explained the first time they are used to avoid confusion.

Appropriate correction is required.

***NON-ART BASED REJECTIONS***

Art Unit: 1817

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors as well as antecedent basis problems. Claims 1-6 fail to recite clear, distinct and positive method steps. Finally, claims 1-6 imply, rather than positively state, at least one of the two antibodies has at least two binding sites for the target/objective antigen in order for cross-linking or agglutination to occur. Critical limitations should be positively stated, not merely implied.

The following language is suggested for applicants' consideration as a basis for more idiomatic claims. Please note that the following suggestion is a basic framework only and will NOT obviate all of the rejections against the claimed invention.

1. An agglutination immunoassay for determining a target antigen in a test sample comprising:
  - (a) sequentially contacting the test sample with
    - (i) a solid phase antibody which specifically binds to a first binding site on the target antigen, wherein said solid phase antibody is immobilized on an insoluble carrier particle, and
    - (ii) a liquid phase antibody which specifically binds to a second binding site on the target antigen, wherein said second binding site is different from said first binding site

Art Unit: 1817

thereby forming an agglutinate comprising said solid phase antibody, said target antigen and said liquid phase antibody; and,

(b) optically measuring the rate of formation of said agglutinate to determine the presence or amount of said target antigen in said test sample.

2. The immunoassay according to claim 1 wherein said optical measuring comprises spectrophotometrically measuring decreasing light transmission due to increased formation of said agglutinate.

3. The immunoassay according to claim 1 wherein the amount of said target antigen is determined from a calibration curve.

Analogous suggestions apply to claims 4-6.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Crosslinking of the antigen-antibody complexes in order to form an agglutinate is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Unless at least one of the two antibodies has at least two binding sites for the target antigen no agglutinate comprising the insoluble carrier particle can be formed.

#### ***ART BASED REJECTIONS***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1817

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cragle et al. (WO 85/02258).

Cragle et al. describes an improved nephelometric immunoassay for an antigen in fluid sample comprising contacting the sample with both a solid phase antibody and liquid phase antibody therefore and measuring the amount of formed complexes, i.e. agglutinates. Thus, Cragle et al. discloses substantially the same invention as claimed. In the alternative, no patentable difference is seen.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Derwent Abstract Accession Number 94-295892/199437 (which corresponds to EP 0 617 285, IDS reference AL).

According to the Derwent Abstract, German document EP 0 617 285 determines an analyte (I) (i.e. objective antigen) in a liquid sample comprising binding it to a specific receptor

Art Unit: 1817

(R1) which is immobilized on a particulate material (i.e. immobilized antibody), present in a sample. The new feature is that the sample also contains a soluble receptor (R2) (i.e. free antibody), specific for (I) and having at least two binding sites of (I). The method is used to determine (I) by immunoprecipitation (nephelometry or turbidimetry, i.e. an agglutination reaction). Advantageously, using a mixture of R1 and R2 is a simple way to reduce or eliminate interference from the Hook effect. Sensitivity in the rising part of the Heideberg curve is improved; the max. is shifted to higher (I) concentrations and further increases in (I) concentration cause a much smaller fall in the curve. Thus, the Derwent Abstract of EP 617 285 discloses substantially the same invention as claimed. In the alternative, no patentable difference is seen. Please note that the original EP document will be substituted for the Derwent Abstract when a full English translation of the EP document is obtained by the Examiner.

### ***REMARKS***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carol A. Spiegel whose telephone number is (703) 308-3986.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula K. Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

***ART UNIT TO BE CHANGED***

Serial Number: 08/893,759

Page 7

Art Unit: 1817

Effective February 7, 1998, the Group and/or Art Unit location of your application in the PTO will change. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

Carol A. Spiegel  
February 3, 1998

*Carol A. Spiegel*  
**CAROL A. SPIEGEL**  
**PRIMARY EXAMINER**  
**GROUP 1800**